UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

GAMBRO SUPPLY CORP. f/k/a
REN SUPPLY CORPORATION

Defendant.

Plaintiff,

4:04CR00660DJS

PLEA AGREEMENT, GUIDELINES RECOMMENDATIONS AND STIPULATIONS

Come now the parties pursuant to Section 6B1.4, Sentencing Guidelines and Policy Statements (October 1987), and the Administrative Order of the United States District Court for the Eastern District of Missouri ("Court") (January 2, 1991) and hereby stipulate and agree as follows:

1. THE PARTIES:

The parties to this plea agreement ("Agreement") are defendant Gambro Supply Corp. formerly known as REN Supply Corporation ("Defendant"), by and through its attorney Thomas F. Carlucci of Foley & Larder LLP, the United States Department of Justice ("Department of Justice") and the United States Attorney's Office for the Eastern District of Missouri ("U.S. Attorney's Office") (collectively the Department of Justice and the U.S. Attorney's Office are referred to as the "United States"). This document and the agreements, recommendations and stipulations contained herein do not and are not intended to bind any governmental office or agency other than the United States Department of Justice and all U.S. Attorney's Offices in all districts throughout the United States, including the U.S. Attorney's Office for the Eastern District of Missouri. It is understood by the parties that the Court is neither a party to nor bound by the agreements, recommendations and stipulations contained herein.

2. THE PLEA AGREEMENT:

- A. The Plea: The Defendant voluntarily agrees to waive indictment and plead guilty to a one count Information, attached hereto, charging it with executing a health care fraud scheme in violation of 18 U.S.C. § 1347.
- **B.** No Further Prosecution: The United States agrees that, other than the single charge contained in the Information, it will not further prosecute Defendant or Gambro Healthcare, Inc. ("Gambro"), and Gambro's current and former parents, brother and sister corporations, indirect, direct, wholly-owned and partially-owned subsidiaries, including any joint ventures involving the operation of dialysis clinic(s) in which Gambro or its subsidiaries have or had an ownership interest, and the predecessors, successors and assigns of any of them (collectively the "Gambro Entities"), as follows:
 - 1. For conduct that is described in the attached Information;
 - 2. For conduct described as Covered Conduct in the civil settlement agreement entered contemporaneously herewith between Gambro and the United States ("Civil Settlement Agreement");
 - 3. For conduct not otherwise described in this Paragraph 2.B. which was known and reviewed by the U.S. Attorney's Office for the Eastern District of Missouri, prior to the acceptance of Defendant's guilty plea by the Court; and
 - 4. Notwithstanding any other provision herein, explicitly excepted from the United States' declination of further prosecution is the investigation by the U.S. Attorney's Office for the Eastern District of New York, but only as it relates to: (a) the submission of claims for parathyroid hormone ("PTH") testing; (b) the evaluation and selection of products to test for PTH levels; and (c) any relationship with, and/or remuneration received from, Nichols Institute Diagnostics, Inc.
- **C.** Conditions for Declination: The United States' foregoing declination of prosecution is contingent on:

- 1. The guilty plea of Defendant being accepted by the Court, and not withdrawn:
- 2. Defendant's performance of all the obligations as set forth in this Agreement; and
- 3. Gambro's performance of all obligations as set forth in the Civil Settlement Agreement. A breach of the Corporate Integrity Agreement ("CIA"), which is included by reference in the Civil Settlement Agreement, does not constitute a breach of this Agreement, and any disputes arising under the CIA shall be resolved exclusively through the dispute resolution procedures of the CIA; and
- 4. Gambro's cooperation as set forth in the Cooperation and Confidentiality Agreement between Gambro and the U.S. Attorney's Office for the Eastern District of Missouri.

If the conditions listed in this paragraph as 1. through 4., above, are not satisfied, then the United States' declination of prosecution in Paragraph 2.B., above, shall be null and void. However, prior to the United States being released of its promises in Paragraph 2.B., Gambro shall be given notice and an opportunity to cure within a thirty (30) day period its alleged failure to satisfy the conditions listed above.

If the Agreement is nullified, Defendant agrees that it will not assert, plead, argue or otherwise raise any statute of limitations, laches, estoppel, or similar defense to any criminal charges relating to the conduct set forth in Paragraph 2.B above, except to the extent to which a defense would have been available on December 1, 2004.

Defendant understands and agrees that it may not withdraw its guilty plea unless the Court rejects this Agreement and the agreed-upon sentence under either Rule 11(c)(5) of the Federal Rules of Criminal Procedure or any other rule authorizing the Court to reject this Agreement and the agreed-upon sentence.

D. Sentencing Guidelines: The United States and Defendant agree to have the sentence

determined under the United States Sentencing Guidelines ("U.S.S.G.") and agree that the facts that determine the total offense level and the criminal history category, including upward and downward calculations as to Chapter 2—Specific Offense Characteristics; Chapter 3—Adjustments; Chapter 4—Criminal History and Criminal Livelihood calculations will be found by the Court at sentencing by a preponderance of the evidence. Furthermore, the parties agree that the Court may consider any evidence, including hearsay, in determining the appropriate sentence.

The United States and Defendant agree that the following provisions of the 1998 United States Sentencing Guidelines apply to the sentencing of Defendant with respect to the offense alleged in the Information:

- 1. Pursuant to U.S.S.G. § 8C2.4 and 18 U.S.C. § 3571(d), the loss to the United States from this offense for criminal sentencing purposes is \$18,498,049;
- 2. Pursuant to U.S.S.G. § 8C2.5, the culpability score is 4, calculated as follows:
 - (a) a starting score of 5 pursuant to U.S.S.G. § 8C2.5(a);
 - (b) 1 point is added pursuant to U.S.S.G. § 8C2.5(b) (5) because the organization had ten or more employees and an individual with substantial authority condoned or was willfully ignorant of the offense;
 - (c) 2 points are deducted pursuant to U.S.S.G. § 8C2.5(g)(2) because Defendant fully cooperated in the investigation and demonstrated recognition and affirmative acceptance of responsibility for its wrongdoing;
- 3. Pursuant to U.S.S.G. § 8C2.6, the applicable range for the multiplier is 0.8 to 1.6, and appropriate multiplier to be applied to Defendant is 1.3515;
- 4. The parties agree there is no basis for either an upward or downward departure under the Sentencing Guidelines; and
 - 5. Defendant and the United States both acknowledge that the loss figure

cannot be determined with precision and that the loss figure of \$18,498,049 for criminal sentencing purposes is a reasonable, good faith estimate.

- **E.** Agreed Disposition: The United States and Defendant agree and stipulate pursuant to Fed. R. Crim. Proc. 11(c)(1)(C) the following sentence is the appropriate disposition of the Information:
 - 1. A criminal fine in the amount of twenty-five million dollars (\$25,000,000) to be paid within three (3) days of sentencing;
 - 2. A mandatory special assessment of \$400 pursuant to 18 U.S.C. § 3013(a)(2)(B), which shall be paid to the Clerk of Court at the time of sentencing; and
 - 3. The parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a restitution order outweighs the need to provide restitution to the victims in this case. See 18 U.S.C. § 3663(a)(1)(B)(ii). Further, the Medicare program, a victim, will be recompensed fully from the amounts that will be paid as part of the Civil Settlement Agreement. Therefore, the United States agrees it will not seek a separate restitution order as part of the resolution of the Information, and the parties agree the appropriate disposition of this case does not include a restitution order.
- F. Effect on Other Governmental Agencies: The Defendant has discussed with defense counsel and understands that nothing contained in this Agreement is meant to limit the rights and authority of the United States to take any tax, civil, or administrative action against the Defendant, including but not limited to any listing, debarment, or exclusion proceedings to restrict rights and opportunities of the Defendant to contract with government agencies. Further, any recommendation in this Agreement as to the amount of loss or restitution is not binding on parties in any civil or administrative proceedings.
- G. Civil and Administrative Liability: Defendant's civil and administrative liability for the Covered Conduct is resolved as set forth in the Civil Settlement Agreement.

H. Effect of Bankruptcy on Fines or Restitution: The Defendant hereby stipulates that any fine or restitution obligation imposed by the Court is not dischargeable in any case commenced by the Defendant or the Defendant's creditors pursuant to the Bankruptcy Code. The Defendant agrees not to attempt to avoid paying any fine or restitution imposed by the Court through any proceeding pursuant to the United States Bankruptcy Code, and stipulates that enforcement of any fine or restitution obligation by the United States or a victim is not barred or affected by the automatic stay provisions of the United States Bankruptcy Code (Title 11, United States Code, Section 362).

3. STIPULATION OF FACTS RELEVANT TO SENTENCING:

The parties stipulate and agree the facts in this case are set forth in the attached Information, and the United States would prove these facts beyond a reasonable doubt. The Defendant and the United States agree the facts set forth in the Information are true and may be considered as "relevant conduct" pursuant to Section 1B1.3 of the Sentencing Guidelines.

4. ELEMENTS OF THE OFFENSE:

The Defendant fully understands that the elements of the crime of executing a health care fraud scheme, in violation of 18 U.S.C. § 1347, with which Defendant is charged in Count I of the Information and which Defendant admits committing, are as follows:

- (a) the defendant knowingly and willfully;
- (b) executed a scheme to defraud;
- (c) a health care benefit program;
- (d) in connection with the delivery of, or payment for, health care benefits, items or services.

5. ACKNOWLEDGMENT AND WAIVER OF THE DEFENDANT'S RIGHTS:

The Defendant acknowledges and fully understands the following rights: the right to plead not guilty to the charges; the right to trial by judge; the right to be tried by a jury in a public and speedy trial; the right to file pre-trial motions, including motions to suppress evidence; the

right at such trial to a presumption of innocence; the right to require the United States to prove the entire case against the Defendant beyond a reasonable doubt; the right not to testify; the right not to present any evidence; the right to be protected from compelled self-incrimination; the right at trial to confront and cross-examine adverse witnesses; the right to testify and present evidence; and the right to compel the attendance of witnesses. The Defendant further understands that by this guilty plea, the Defendant expressly waives all the rights set forth in this paragraph. The Defendant understands that it has the right to be represented by counsel at trial and at every other stage of the proceeding. The Defendant's counsel has explained these rights and the consequences of the waiver of these rights. The Defendant fully understands that, as a result of the guilty plea, no trial will occur and the only action remaining to be taken in this case is the imposition of the sentence.

The Defendant has also been fully apprised of its right to appeal by its attorney and fully understands it has a right to appeal its sentence under 18 U.S.C. § 3742. However, in the event the Court accepts this Agreement, both Defendant and the United States hereby waive all rights to appeal all non-jurisdictional issues, including but not limited to: any issues relating to pre-trial motions, hearings and discovery; any issues relating to the negotiation, taking or acceptance of the guilty plea or the factual basis for the plea; any issues relating to any right to indictment, jury trial, and burden of proof on sentencing facts; any issues relating to the applicability and validity of the Sentencing Guidelines; and, whatever sentence is imposed, any issues relating to the establishment of Total Offense Level or Criminal History Category determined by the Court, except that the parties reserve the right to appeal from any Chapter 5 upward or downward departure from the Guidelines range if such departure is not agreed to in this document.

The Defendant fully understands that it may possess certain rights under the Sixth Amendment of the federal constitution to have a jury find beyond a reasonable doubt every fact that determines the sentence. The Defendant further understands that per *Blakely v. Washington*, 124 S.Ct. 2531 (2004) and *Apprendi v. New Jersey*, 530 U.S. 466 (2000), it may have certain

claims that the U.S.S.G. are unconstitutional in whole, or in part. The Defendant, after consultation with its attorneys, hereby waives such rights and claims it possesses or may possess under the Sixth Amendment and/or under *Blakely* and *Apprendi*.

The Defendant is fully satisfied with the representation received from defense counsel.

The Defendant has reviewed the United States' evidence and discussed the United States' case and all possible defenses and defense witnesses with defense counsel. Defense counsel has completely and satisfactorily explored all areas which the Defendant has requested relative to the United States' case and any defenses.

6. COURT NOT BOUND BY PLEA AGREEMENT:

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the Court. Defendant's plea will be tendered pursuant to Fed. R. Crim. Proc. 11(c)(1)(C). Defendant may withdraw its plea of guilty if the sentencing judge rejects this Agreement. If the sentencing judge rejects this Agreement, this Agreement shall be null and void at the option of either the United States or Defendant.

7. DEFENDANT'S REQUEST FOR IMMEDIATE SENTENCING:

Defendant intends to seek sentencing by the Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence Defendant immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. Defendant understands that the decision to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the Court.

8. DEFENDANT'S CRIMINAL RECORD:

The criminal record of the Defendant as known to the parties at this time is as follows: None.

9. PRESENTENCE REPORT AND SENTENCING:

Should the Court decide not to sentence Defendant immediately after the Rule 11 plea

hearing and refer the matter to the Probation Department, then as to the sentence to be imposed upon the Defendant, pursuant to Fed. R. Crim. Proc. 32, each party shall have the right to comment on the report of Defendant's presentence investigation and the right to introduce testimony or other information relating to any factual inaccuracies contained in the report. The parties reserve the right to comment on the application and calculation of the sentencing guidelines to the offense to which Defendant will plead guilty and to allocution at the time of sentencing regarding the appropriate sentence to be imposed. Each party also reserves the right to bring any misstatements of fact concerning this matter made either by the other party or on that party's behalf, to the attention of the Court at the time of sentencing.

10. STANDARD OF INTERPRETATION:

In interpreting this Agreement, any drafting errors or ambiguities shall not automatically be construed against any party, whether or not the party was involved in drafting this Agreement.

11. CORPORATE AUTHORIZATION:

Defendant shall provide to the U.S. Attorney's Office and the Court a certified copy of a resolution of the Board of Directors of Defendant affirming the Board has: (1) reviewed the Information and the Agreement; (2) consulted with legal counsel in connection with this matter; (3) voted to enter into the Agreement; and (4) voted to authorize a designated corporate officer to execute the Agreement and all other documents necessary to carry out the provisions of the Agreement.

12. ENTIRE AGREEMENT:

This Agreement constitutes the entire agreement between the Defendant and the United States, and no other promises or inducements have been made, directly or indirectly, by any agent of the government, including any attorney for the United States, concerning any plea to be entered in this case or the agreements, recommendations or stipulations contained herein. In addition, the Defendant states that no person has, directly or indirectly, threatened or coerced the Defendant to do or refrain from doing anything in connection with any aspect of this case,

including entering a plea of guilty. The Defendant's agreements, recommendations and stipulations as set forth above are made in exchange for the United States' agreements. recommendations and stipulations set forth in this Agreement. The Defendant acknowledges that this guilty plea is made because the Defendant is in fact guilty of the conduct specified in the Information.

13. CONSEQUENCES OF FURTHER CRIMINAL CONDUCT BY DEFENDANT:

The Defendant agrees that the United States shall be released from any obligations and limits on its power to prosecute as set forth above in Paragraph 2.B. above, if the Defendant engages in any criminal activity between the entry of the guilty plea and the sentencing.

DATE: December 1, 2004

James G. Martin, United States Attorney Eastern District of Missouri

Assistant United States Attorney 111 South 10th Street, 20th Floor

St. Louis, MO 63102

DATE: December 1, 2004

Dorothy L. McMurtry, United States Department of Justice

DATE: Vecember 1, 2004

Gambro Supply Corp.

By:

Secretary, Gambro Supply

DATE: Dumber 1, 2004

Foley & Lardner LI

Carlucci Attorneys for Gambro Supply Corp.